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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/667,533 | 09/22/2003 | Francis J. Fry | 6930-67263 | 9932 |

23643 7590 02/27/2006

BARNES & THORNBURG
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

| EXAMINER | |
|---|---|
| PEFFLEY, MICHAEL F | |
| **ART UNIT** | **PAPER NUMBER** |
| 3739 | |

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/667,533 | FRY ET AL. | |
| | Examiner | Art Unit | |
| | Michael Peffley | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13 and 27-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 27-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and arguments, received January 6, 2006, have been fully considered by the examiner. In particular, applicant's amendments to the specification have obviated the objection. The following is a complete response to the January 6, 2006 communication.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 10, 11, 27, 28, 31, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al (5,292,484) in view of the teaching of Lesh et al (6,024,740).

Marcus et al disclose a catheter having an ultrasound transducer for treating tissue. Marcus et al specifically disclose the steps of providing the catheter to a tissue location and oriented in the desired orientation with respect to the tissue (col. 4, line 40 through col. 5, line 22). Marcus et al go on to disclose that after treating, the tissue is again mapped to determine the efficacy of the treatment, and, if more treatment is necessary, the transducer is again oriented such that an effective block (i.e. treatment) may be performed. Marcus et al therefore teach of performing multiple orientation steps for the transducer, but fail to explicitly disclose the steps of varying longitudinal and angular orientations as recited in the instant application claims.

The examiner maintains that the demands of the particular procedure would dictate the specific orientation of the catheter, and that those demands would obvious result in orientation of the catheter in accordance with the limitations of the application claims. That is, after a single treatment of tissue, if mapping of the heart tissue indicates that tissue located longitudinally from the device requires another treatment, then the catheter would obviously be moved longitudinally as necessary. Similarly, if the catheter were needed to be moved angularly to treat a particular treatment area, then such a move would obviously be made to perform a successful procedure.

The Lesh et al reference is being provided to show that it is generally well known in the art to provide a catheter using ultrasound transducers for the treatment of heart tissue to various tissue locations. In particular, Lesh et al specifically teach that lesions are made at various locations within heart tissue, which locations inherently have different longitudinal and angular directs, and also indicates that multiple treatments may be made at a single site. Again, the examiner maintains that the specific combination of the movements of the transducers (i.e. either longitudinally, angularly or both) would depend on the efficacy of the treatment and the need for further treatment.

To have utilized the Marcus et al device in a procedure with any reasonable orientation of the ultrasound transducers throughout separate applications of energy in a given procedure is deemed to be an obvious consideration for one of ordinary skill in the art and obviously dependent upon the needs of the particular procedure. Moreover, Lesh et al generally teach of the well known multiple orientations of ultrasound

transducers in a similar procedure thereby inherently arriving at the various combinations of orienting the transducers angularly and longitudinally.

Claims 6-9, 12, 13, 29, 20, 32, 33, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484) and Lesh et al ('740) as applied to the claims above, and further in view of Ingle et al (6,216,704).

The Marcus et al device, as well as the teaching of Lesh et al, has been addressed in the previous rejection. Marcus et al provides an array of ultrasound transducers, but fails to specifically disclose that the array includes a variable focal length for treating tissue at different depths.

Ingle et al disclose another ultrasound device used to treat tissue. In particular, Ingle et al teach that it is known to provide the ultrasound array with either a fixed focal length or a variable focal length to treat tissue to various depths (see col. 25, lines 10-30 and col. 27, lines 23-33).

To have provided the Marcus et al ultrasound array with a variable focus length to control the treatment depth would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Ingle et al.

***Response to Arguments***

Applicant's arguments filed January 6, 2006 have been considered but are not deemed persuasive.

With regard to claims 1-5, 10, 11, 27, 28, 31, 34 and 35, applicant merely states that the prior art does not disclose nor suggest that which is set forth in the claims.

Applicant has not stated what specifically is not taught or disclosed in the combination of the Marcus and Lesh references. As detailed in the above rejection, the examiner maintains that the prior art does disclose that which is set forth in the claims, and the rejection is maintained.

Applicant contends that the Ingle et al ('704) reference is not prior art because the parent applications, Ingle et al (6,081,749) and Ingle et al (6,035,238) do not disclose or suggest using an ultrasound transducer having a variable focal length. The examiner disagrees. Ingle et al (6,081,749) does teach the use of an ultrasound transducer having a variable focal length. In particular, Ingle et al ('749) disclose at column 13, lines 28-30 that "High intensity ultrasound is able to heat tissues at a distance from the probe, and may be focused to apply the most intense heating at a particular treatment site" (emphasis added). Clearly, Ingle et al ('749) disclose an ultrasound transducer with a focal length that may be adjusted (i.e. varied) to treat a particular treatment site. The examiner maintains that proper support is provided in the Ingle et al ('749) reference and that the examiner may rely on the August 13, 1997 filing date of the ('749) reference to teach the claimed subject matter. Accordingly, the rejection is maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 21, 2006